Episode Book

EPISODE #6329

How Israel Actually Regulates Foreign Drugs

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SYNOPSIS

Israel's Health Ministry does not simply rubber-stamp decisions from the FDA or EMA. Regulators rely on unredacted assessment reports from six recognized authorities, requiring local dossiers to remain practically identical to foreign filings. The regulatory process, local packaging rules across four languages, and recent reliance pilot tracks shorten review times from hundreds of days down to seventy, demonstrating how small nations balance foreign regulatory reliance with their own statutory oversight.

TRANSCRIPT



Corn

Does Israel just copy the FDA? That's the assumption Daniel has lived with, and plenty of people share it: a drug gets approved in the United States, and a little later it appears in a Jerusalem pharmacy, no questions asked. The common assumption is that Israel rubber-stamps the FDA, and it turns out the real story is more interesting than that. Daniel wants to know how a prescription drug actually gets from the manufacturer to an Israeli shelf, and how much of the journey is borrowed from foreign regulators.



Herman

The borrowing is real. It's just not the kind people picture. Israel's own Health Ministry staff published a paper in BMJ Open in twenty twenty-three, and one line in it says FDA or EMA approval "does not pave the way to automatic approval in Israel." Ministry people wrote that about their own system.



Corn

Which is a strange thing to publish if you were rubber-stamping.



Herman

A little defensive, yes. We covered the why of this a while back, in the episode on why small nations re-review medicine: sovereignty, the health budget, all that. Today is the machinery. The paperwork, the clocks, the lists.



Corn

Start with the law. Who says a drug has to be registered at all?



Herman

The Pharmacists Ordinance, the new version of it from nineteen eighty-one. The registration section is forty-seven A, added in nineteen ninety-nine, though the registry itself goes back to nineteen sixty-four. The Director-General of the Ministry of Health keeps the register, and nobody may manufacture, market or direct the use of a preparation unless it's on it. The same section has the Director-General classify each product as prescription or not.



Corn

And the person who actually opens your file?



Herman

An institute inside the ministry, the Institute for Standardization and Control of Pharmaceuticals. ISCP. It sits in Jerusalem, and the people there are who you deal with. It's also a member of PIC/S, the club of regulators that inspect manufacturing plants and accept each other's inspection standards. I've seen the accession given as about two thousand nine, but the sources I found disagree on the exact date.



Corn

So there's a registry, an institute, and a rule that you can't sell without being in the book. Fine. What goes in the file?



Herman

The full thing. The common technical document, all five modules, which is the international dossier format: administrative papers, quality, nonclinical, clinical. Then on top, if you're leaning on a foreign approval, you add the foreign approval letter, a certificate of pharmaceutical product from that regulator, and the foreign regulator's own assessment reports, unredacted.



Corn

Unredacted. So the ministry reads over the FDA's shoulder.



Herman

It reads what the FDA's reviewers wrote about the drug. Including the parts a company would rather not have highlighted. And there's a signature I like: an appointed pharmacist in Israel has to declare that the quality part of the Israeli dossier is identical to the foreign one.



Corn

Identical. Not similar.



Herman

Identical, with a short list of permitted differences. The site that releases the batches in Israel, the site that repeats the quality testing, and on the slower tracks the stability data and the primary packaging. Change anything else, say the indication or the dose, and you've left the fast lane. You're a regular application.



Corn

So "reliance" means "photocopy". I'd always pictured a regulator saying "we trust you" and leaving it there.



Herman

Trust with a comparison tool, more or less. Though I practised long enough to know that photocopies don't stay identical on their own. Somebody has to keep them that way.



Corn

Dryly noted, doctor.



Herman

Which regulators count? Here I'd like you to guess, Corn. How many foreign authorities can an applicant lean on?



Corn

Two. The FDA and the Europeans. Maybe the British, out of habit.



Herman

Six. The FDA, the European Medicines Agency but only through its centralized procedure, the Australian TGA, Swissmedic, Health Canada and the British MHRA. Japan isn't on the list that I read, which surprised me, because people assume Japan is on every list.



Corn

Six regulators and I got three of them. I'll take it. Why those six, though? Is it a quality thing, or a who-do-we-already-talk-to thing?



Herman

I can't tell you the ministry's reasoning. My guess is both: they're regulators with big reviewing staffs and published assessment reports, and the ministry already trades information with them. But that's my inference, not a statement from the ministry.



Corn

Why, though? Why not any European approval?



Herman

Because a national approval from one member state is one country's opinion. Only the single EU-wide procedure counts, where the whole agency has looked at it.



Corn

Hang on. Episode four ninety-six said something about an Access Consortium. Australia, Canada, Singapore, Switzerland, the UK. Israel was supposedly on its way in.



Herman

We couldn't substantiate that. Nothing I found connects Israel to Access. The six authorities on the Israeli list are individual regulators, and my reading is that Israel has information sharing with them, not membership of that club. If anyone has seen a source, I'd like to know.



Corn

Noted, once. Moving on.



Herman

There are local requirements too, and they're less glamorous. You need a named pharmacist in Israel with a licence number. The product needs a Hebrew name. A foreign manufacturer needs a local registration holder, and according to one regulatory consultancy, each shipment needs an import permit, and pharmacovigilance has to be handled locally. That last bit is the consultancy's summary, not the ministry's.



Corn

Hebrew name. Ministry staff decide whether "Lipitor" is allowed to be Lipitor in Hebrew letters.



Herman

Transliteration is generally fine, as far as I know. What I can't tell you from what I read is how fussy they get.



Corn

Is there more on the box than the name?



Herman

Reportedly the labelling rules require the preparation name in Hebrew, Arabic, English and Russian, and brand names too since two thousand twelve. That's from a law firm's articles, so I'd treat the exact detail with some care. But the idea is a box built for four reading publics.



Corn

Four languages on a box the size of a matchbook. Somebody's typography is suffering.



Herman

The patient leaflet is the bigger problem, I'd think. And the box is the end of a longer story, because before any of that the ministry has to be satisfied about where the thing was made. Hm, let me narrow that. The inspection of factories is a separate system, and the Israeli institute belongs to the international scheme where regulators inspect plants and accept each other's reports. The consultancy I read says batch release can be done locally, and that's where the permitted difference in the release site comes from.



Corn

So the ministry checks the paper, trusts the factory inspector abroad, and then someone in Israel signs off the actual batch.



Herman

That's how I read it, though that part came from a consultancy summary and not a ministry document, so I'd hold it loosely.



Corn

My objection, then. If the dossier has to be a copy, then Israel is a follower. Whatever the FDA decides, the ministry inherits, with extra Hebrew.



Herman

That's the part I'd push back on, and there's a study. Ministry researchers looked at two hundred and twenty-six applications from twenty fourteen to twenty sixteen. All of those reached an advisory committee, the Advisory Committee on Drug Registration, which is independent clinical review. About one in eight needed more than one discussion at that committee. And those were the ones that later went through the most major post-approval changes.



Corn

So when the committee argued twice, the label got reworked after the fact.



Herman

That's the pattern. I wouldn't call it proof the committee was right. It does show the committee wasn't decoration.



Corn

Herman, a question, since you practised here. When you handed a family a prescription, did you ever think about any of this?



Herman

Never once. That's what a registry is for. You think about the drug, and you assume somebody has already thought about the box. Though I'll admit I never wondered how long the box took to arrive. Corn, you've never needed a prescription in your life, but suppose you did: would you rather the ministry took longer and found something, or moved fast on the FDA's say-so?



Corn

Longer. I'm a sloth. Slow is a lifestyle, and I've never once been hurried into anything I regretted.



Herman

Slow is fine until the leaflet. You have never read one in your life.



Corn

The leaflet reads me. Anyway. And now, our regular caller with the travel reviews. Clive, what have you got for us?

C

Clive

One-Star Getaways. In Naples I stayed at the Hotel Belvedere Finta, where the room promised a sea view and delivered a sea view, framed, hanging over the bed, slightly crooked. One star.

C

Clive

The lift had a sign saying it was out of order, which was honest of it, and the breakfast cornetto was a day old and proud of it. For anyone looking for a disappointing trip this winter, I recommend it warmly.



Herman

Corn, I can see you pricing the flight. No.



Corn

The crooked view has a certain integrity.



Herman

Back to the tracks, because this is where the reform lands. In March twenty twenty-five the ministry introduced three reliance tracks, as a two year pilot. Track A is seventy working days, for an original or biosimilar product approved in the last three years by at least two of the recognized authorities, with the FDA or the European procedure among them. Track B is a hundred and twenty working days, for an original or biosimilar approved within five years by one authority. Track C is also a hundred and twenty, for a generic of something already registered in Israel.



Corn

So a hundred and twenty days is about four months. For a drug someone has already approved elsewhere.



Herman

Four months against what it used to be. A journalist's figure from the time put the old average at roughly two hundred and seventy days, and the older tracks anywhere from a hundred and eighty to two hundred and seventy. The American Chamber of Commerce told a Knesset committee in twenty twenty-two that it could take four hundred to six hundred days after FDA or European approval, but that's an advocacy group and I don't know how they measured it.



Corn

Four hundred to six hundred days is over a year, and up to nearly two. I'd have moved house.



Herman

The clock matters, and so does what's inside it. A preliminary check of up to twenty working days. On Track A, one question letter from the ministry by day forty. On B and C, up to two. The applicant gets thirty working days to answer, and the clock ends with a certificate or a rejection, not with a pleasant email.



Corn

So who does this actually speed up? The company that sells in Boston and Basel and then fills in the Israeli form.



Herman

Anyone whose file is the same file. And products that rely on new technology the ministry has never approved, cell and gene therapies, are excluded from reliance. Those get the full treatment, and there's a separate lane of a hundred and eighty days for innovative products that aren't relying on anyone.



Corn

Fine. What happens with a drug nobody abroad has approved? Is it illegal?



Herman

Not barred by law. It goes through the regular route. One account from around two thousand two said the ministry historically waited for the FDA to finish before it moved, but that's old, and a snippet. I'd say in practice the foreign approval is a gate even where the law doesn't make it one.



Corn

A gate that isn't written down. Those are the best kind of gate.



Herman

Would you have guessed the idea is that old? There's a curiosity in the history. The nineteen eighty-one Ordinance, at least in the consolidated text I could read, already has a clause saying a product identical to one approved by the FDA or an EU authority can be registered on proof of approval, with the Director-General deciding within seventy days. Whether that wording survives in today's text, I can't tell you. But seventy working days is not far from seventy days.



Corn

Not that old, but older than I'd have said. So the twenty twenty-five reform is the ministry finally using a power it had on paper for forty years.



Herman

That's one reading. Do you buy it, though? A power sitting unused for decades?



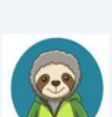
Corn

I buy it. Ministries are the only places where a fast lane can sit unopened for forty years and still be called a plan.



Herman

The same ministry also keeps a priority procedure, capped at a hundred and fifty days, for products of major public benefit or big savings. The Hebrew press reported that, so I'd say the cap is the ministry's intention, not a track record.



Corn

A priority lane with a hundred and fifty day cap. Priority for who, exactly? Everyone's drug is a major public benefit to somebody.



Herman

The ministry decides, which is the answer to most questions in this episode.



Corn

Let me flip it. You're the manufacturer. You've cleared registration. Do do you have a drug on the shelf now?



Herman

No, and the more I read, the more this is the thing outsiders miss. Registration says the drug may be sold. It doesn't set the price and it doesn't decide who pays. Those are two other gates.



Corn

Gate two being the price.



Herman

The ministry sets a maximum price for every registered drug, reimbursed or not. Under the rules I read, from twenty nineteen, a new drug's maximum price is the average of the three lowest wholesale prices among seven European countries: England, Germany, the Netherlands, France, Belgium, Spain and Hungary. That's the framework as it stood in twenty nineteen, so don't hold me to it as current. Generics were frozen at their mid twenty eighteen level.



Corn

So Israel borrows its prices from seven European countries and its approvals from six regulators, and none of the seven are in the six.



Herman

Not the United States, anyway, which I enjoy. For prices it looks to Europe, for evidence it looks to the FDA and everyone else.



Corn

A donkey who enjoys a table. Gate three?



Herman

Funding. A public committee, doctors, health funds, the finance ministry, members of the public, decides each year what goes into the health basket, the list of drugs the funds must cover. In twenty eighteen that was around a hundred and thirty-five items for about four hundred and sixty million shekels. The latest round, reportedly, is six hundred and fifty million a year with most items effective last March.



Corn

And if your drug isn't in the basket?



Herman

The health funds aren't obliged to pay. There are exceptions committees, and there's Regulation twenty-nine.



Corn

Which sounds like a loophole with a number.



Herman

It's the regulation under the Pharmacists Regulations from nineteen eighty-six that allows import of an unregistered product for an individual patient. A physician fills out what's called a Form twenty-nine, which is treated as a prescription, reportedly valid for six months, and a district pharmacist approves it for a community pharmacy. That page of the ministry wouldn't load for me, so the details are secondhand.



Corn

So you can get a drug the ministry hasn't registered, one patient at a time.



Herman

And in February twenty twenty-four there was a temporary scheme letting the health funds import up to ten generic or biosimilar products already registered in recognized markets, when the original is registered in Israel and two or fewer products are registered for that active ingredient. The permit becomes automatic after forty-five working days, up to a year. That one I read in an excerpt from a legal guide.



Corn

Automatic after forty-five days. "Automatic" meaning nobody objected.



Herman

Yes, silence as approval. Parallel import has a similar history. From around the year two thousand, permits could go to anyone, not only the manufacturer's agent, and the minister of the day forecast a twenty percent price drop. A forecast, though. I don't know what actually happened.



Corn

What I can't get is how little of this has a named drug in it. You'd think there'd be one where somebody wrote the FDA date and the Israeli date side by side.



Herman

I looked. A cancer immunotherapy from BeiGene was announced as approved by the ministry in September twenty twenty-four, for a type of oesophageal cancer, and I couldn't confirm the American or European dates to compare. Nobody seems to have published the pilot results either, how many applications, how many days they really took.



Corn

So the verdict on the pilot is "ask again next spring".



Herman

Two years was the number mentioned, so spring of next year at the earliest.



Hilbert

Casio F-ninety-one W. Thirty-nine shekels. Avraham charged me forty-five and I let it go for a decade. While you two were on the Hebrew name, I rang him and had him read a box of my tablets down the phone in all four languages. Hebrew, Arabic, English, Russian. I timed it. Two minutes eleven.



Herman

That's a long time for one lid.



Hilbert

Russian was the slow one. Avraham's father Shimon did all four in fifty-eight seconds, and Avraham still brings it up. Corn, you said four months. A hundred and twenty working days is nearer five and a half. I did it on the back of a delivery note. Twenty-four weeks.



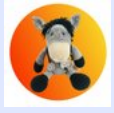
Corn

Working days. Fair, that one's mine.



Hilbert

And Avraham says anything not on his shelf is nine days from the wholesaler. Registered, approved, in the book. Nine days.



Herman

That's after all three gates, Hilbert. Registration, then the price, then the import permit on each shipment for the foreign makers, then a wholesaler. The reform shortens the first gate. It doesn't touch the nine days.



Corn

So the fast lane ends at a wholesaler with a van. Seventy working days to be told you may sell it, then nine ordinary days to get it across town. The second number is the one a patient notices.



Herman

Nothing in the dossier fixes that. The ministry's clock stops at the certificate.



Hilbert

Meir drives it. Same nine days. Different gate, fine.



Corn

Daniel's question gets a better answer than yes or no, then. An FDA or EMA approval is the ticket to the front of the queue, but the file has to be a copy, and the ministry still runs its own committee and sets its own price.



Herman

The open question is the next two years. If the pilot comes back with fast tracks and no safety surprises, I'd expect it to become the default, and then the delay that matters is everything after the certificate, the nine days nobody's clock measures.



Corn

Thanks to our producer Hilbert Flumingtop for keeping the show running.



Herman

This has been My Weird Prompts. If you enjoyed it, find us at my weird prompts dot com.



Corn

See you tomorrow.